AMENDMENTS TO THE CLAIMS

IN THE CLAIMS

Please amend the claims as follows:

Claims 1-26 (cancelled).

27. (currently amended) Leflunomide, prepared by a process comprising the steps of:

a) providing 5-methylisoxazole-4-carboxylic acid chloride; ~~and~~

b) contacting the 5-methylisoxazole-4-carboxylic acid chloride with 4-trifluoromethylaniline in the presence of an alkali metal or alkaline-earth metal bicarbonate in an acylation solvent system comprising at least one solvent component selected from the group consisting of water, ethyl acetate, toluene and dimethyl acetamide~~,~~; and

c) isolating the leflunomide,
wherein the leflunomide has about 150 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

28. (currently amended) The leflunomide of claim 27 wherein 5-methylisoxazole-4-carboxylic acid chloride is provided as crude 5-methylisoxazole-4-carboxylic acid or a residue by:

a) chlorinating 5-methylisoxazole-4-carboxylic acid by contacting it with a chlorinating agent to form crude 5-methylisoxazole-4-carboxylic acid chloride; and

b) optionally evaporating excess chlorinating agent or volatile byproducts of the chlorination under reduced pressure, whereby the evaporation leaves a residue of unevaporated material containing 5-methylisoxazole-4-carboxylic acid chloride.

29. (cancelled)

30. (cancelled)

31. (currently amended) The leflunomide of claim ~~30~~ 27 containing about 100 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

32. (original) The leflunomide of claim 31 containing about 50 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

33. (original) The leflunomide of claim 32 containing about 10 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

34. (original) The leflunomide of claim 27 which is substantially free of 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide.

35. (original) The leflunomide of claim 27 which is substantially free of N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.

36. (currently amended) The leflunomide of claim 27 substantially free of ~~N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide,~~ 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide and N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.

37. (currently amended) A pharmaceutical composition comprising the leflunomide of any one of claims ~~27 through 36~~ 27-28 or 31-36.

38. (original) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 37.

39. (currently amended) A method of treating rheumatoid arthritis comprising administering to a patient in need of such treatment a therapeutically effective amount of the leflunomide of any one of claims ~~27 through 36~~ 27-28 or 31-36.

40. (currently amended) A method of regulating cell proliferation comprising administering to a patient an amount of the leflunomide of any one of claims ~~27 through 36~~ 27-28 or 31-36 sufficient to inhibit cell proliferation.

41. (new) Leflunomide containing about 150 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

42. (new) The leflunomide of claim 41 containing about 100 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

43. (new) The leflunomide of claim 41 containing about 50 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

44. (new) The leflunomide of claim 41 containing about 10 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.

45. (new) Leflunomide which is substantially free of 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide.

46. (new) Leflunomide which is substantially free of N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.

47. (new) The leflunomide of claim 41, which is substantially free of 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide and N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.